In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-619V

Filed: May 1, 2024

MICHAEL SCHWARZ,	*
Petitioner,	*
v.	*
SECRETARY OF HEALTH AND HUMAN SERVICES,	*
Respondent.	*

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for Petitioner
Catherine Stolar, U.S. Department of Justice, Washington, DC, for Respondent

RULING ON ENTITLEMENT[1]

Oler, Special Master:

On May 1, 2018, Michael Schwarz ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*[2] (the "Vaccine Act" or "Program"). The petition alleges that Mr. Schwarz developed transverse myelitis ("TM") as a result of the tetanus, diphtheria, and acellular pertussis ("Tdap") vaccine he received on May 20, 2015. Pet. at 2. After the entitlement hearing held on May 18, 2022, Petitioner clarified that

[1] Because this Ruling contains a reasoned explanation for the action in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Ruling will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

the Tdap vaccine caused him to develop a severe inflammatory reaction characterized by arthralgias. Pet'r's Post-Hearing Brief at 1; Pet'r's Post-Hearing Reply at 3 (reiterating that "Mr. Schwarz has arthralgias that were caused by the vaccine."). Although several different injuries were raised in the expert report and at the entitlement hearing, Petitioner confirmed that he was not alleging an injury of transverse myelitis, brachial neuritis, or chronic fatigue syndrome ("CFS"). *Id.*

Upon review of the evidence submitted in this case, I find that Petitioner has demonstrated he developed arthralgias post vaccination, and that the Tdap vaccine caused this condition. Petitioner is entitled to compensation.

I. Procedural History

Petitioner filed his petition on May 1, 2018. Pet., ECF No. 1. He filed medical records on July 2, 2018 and August 1, 2018 followed by a statement of completion. ECF Nos. 9-12.

Respondent filed his Rule 4(c) Report on April 29, 2019 indicating that the case was not appropriate for compensation under the Vaccine Act. Resp't's Rep. at 1; ECF No. 19.

Petitioner then filed additional medical records and his social security disability file. Exs. 9-14, ECF No. 21; Ex. 15, ECF No. 23. Petitioner filed an expert report from Dr. Yuval Shafrir on March 30, 2020. Ex. 16; ECF No. 33.

On December 4, 2020, Respondent filed a responsive expert report from Dr. Michael Wilson. Ex. A; ECF No. 41.

Petitioner then indicated that he wanted to schedule the case for an entitlement hearing. ECF No. 45. After receiving input from the parties, I scheduled the case for a hearing to take place on May 18-May 19, 2022. *See* non-PDF Scheduling Order dated August 3, 2021.

I conducted an entitlement hearing on May 18-19, 2022. Petitioner filed a post-hearing brief on September 30, 2022. ECF No. 62. Respondent filed a response on January 30, 2023. ECF No. 64. Petitioner filed a reply brief on March 16, 2023. ECF No. 65. The parties indicated the record was complete on April 6, 2023. ECF No. 70. This matter is now ripe for adjudication.

II. Medical Records

On May 1, 2015, prior to Petitioner's Tdap vaccination, Petitioner visited the Walla Walla Clinic to establish care with Dr. Michael Wilcox, his new primary care physician ("PCP"). Ex. 1 at 9. Petitioner's history of present illness ("HPI") describes a five day history of a respiratory illness with sinus congestion, purulent nasal drainage, fever, and malaise. *Id.* Petitioner reported that he had a "long history of fatigue that worsened significantly over the last 4 or 5 months… [and] some associated night sweats insomnia." *Id.* Dr. Wilcox recommended an Adacel vaccine when Petitioner recovered from his present illness. *Id.* at 11.

Petitioner received a Tdap vaccine at the Walla Walla Clinic on May 20, 2015. Ex. 8.

On May 22, 2015, Petitioner presented to the Adventist Health Walla Walla General Hospital emergency department complaining of neck pain and stiffness that had progressively worsened throughout the day as well as difficulty moving his right hand. Ex. 1 at 22. Petitioner noted that his pain was radiating from his bilateral anterior chest, shoulders, and jaw, and was exacerbated by movement. *Id.* The doctor diagnosed Petitioner with an acute strain of his neck muscle. *Id.* at 24. Petitioner's upper extremity reflexes were 2+ on the left and 1+ on the right. *Id.* He also had tenderness to palpation over the anterior shoulder girdle and pain with arm elevation. *Id.* The record documented a consult with an infectious disease doctor; the infectious disease doctor opined: "[patient] could not have contracted tetanus from booster as it is a killed vaccine, and it is highly unlikely [patient] contracted tetanus in absence of wound. Recommends [lumbar puncture] to evaluate for possible meningitis and consider other sources." *Id.* Petitioner's blood test revealed an elevated white blood cell count. *Id.* at 28.

The next day, on May 23, 2015, Petitioner presented to Providence St. Mary Medical Center emergency department complaining of neck stiffness and bilateral hand weakness and pain. Ex. 1 at 31-33. Petitioner reported onset as two days ago, that his arms were weak, and that he was experiencing pain and stiffness in his hands. *Id.* Petitioner also reported ongoing fatigue problems dating back to the beginning of spring. *Id.* His reflexes were 1+ in the upper extremities and 3+ in the lower extremities. *Id.* at 33. Petitioner's C-reactive protein ("CRP") level was high; it measured at 90.70 (reference range ≤ 3.0 mg/L). *Id.* at 36. His white blood count was also high at 13.8 (reference range 4.0-11.0 kK/uL). *Id.* at 34. The doctor noted "most likely this is an inflammatory reaction to the tetanus shot he received" and the final impression was "polyarthralgia and bilateral arm weakness." *Id.* at 33.

Petitioner returned to his PCP Dr. Wilcox on May 26, 2015. Dr. Wilcox noted that Petitioner was taking lorazepam for his insomnia. Ex. 1 at 39. On physical examination, Petitioner had an erythema and swelling of his left forefinger and he noted pictures from Petitioner's cell phone of a migratory erythematous rash. *Id.* at 40. Dr. Wilcox wrote, "It appears that he is suffering from a reaction to his Adacel vaccination. His current symptoms are reported side effects and he has had extensive evaluation otherwise… I recommended a tapering course of prednisone… Continue lorazepam as needed for insomnia." *Id.*

Petitioner returned to Dr. Wilcox on June 5, 2015. Ex. 1 at 42-44. Dr. Wilcox assessed Petitioner as having "arthralgia of multiple sites" and noted that he was experiencing "[c]ontinued generalized and migratory arthralgias following a tetanus vaccination. We discussed alternative inflammatory conditions such as palindromic rheumatism or others. His clinical course continues to be most suggestive of a reaction to his vaccination. He initially did well on the higher dose of prednisone…. If responding, we will set out a slower, more gradual prednisone taper." *Id.* at 43.

On June 30, 2015, Petitioner was seen at Adventist Health by Dr. Cloise Moore. Ex. 1 at 45-46. Dr. Moore noted that Petitioner was being tapered from prednisone but was looking for other treatments to hasten his recovery. *Id.* at 45. Dr. Moore assessed a "probable reaction to the [Tdap]" vaccine. *Id.*

On July 9, 2015, Petitioner saw his PCP for a follow up for "arthralgias and skin symptoms." Ex. 1 at 47. The HPI reads:

> He was evaluated back in May for fatigue and other symptoms. He then developed much worse symptoms of arthralgias and rash following an Adacel vaccination 5/20/15. We started a slow taper of prednisone on 6/5/15, initially 60 mg daily, now down to 15 mg 4 days ago. Arthralgias are doing relatively well. His symptoms seem to flare when he decreases the dose of prednisone, but eventually levels out. He described flushing and abnormal temperature sensations in his hands and groin.

Id. Petitioner complained of joint swelling, but none was observed on physical examination. *Id.* at 48. Under summary, Dr. Wilcox wrote:

> His presentation remains complex with pre-existing symptoms and unclear clinical picture. We could consider an underlying disorder such as seronegative spondyloarthropathy, cryoglobulinemia, Lyme disease, Chronic fatigue syndrome or others. Because he is currently on prednisone, testing would likely be unreliable. We have set out a continued taper of prednisone… We will plan comprehensive laboratory testing [in three weeks]. Consider a rheumatologic evaluation.

Id. at 49.

On July 29, 2015, Petitioner returned to Dr. Wilcox one week after completing his prednisone taper. The medical record notes that Petitioner's arthralgias were improving but that there was some residual wrist discomfort. Ex. 1 at 50. Dr. Wilcox wrote, "Recommended we screen for underlying inflammatory condition." *Id.* at 52. His bloodwork was normal and was negative for rheumatoid factor, Hepatitis C, Lyme disease, ANA antibodies,[3] anti-CCP antibodies,[4] and cryoglobulin.[5] *Id.* at 56-64. His C-reactive protein now measured < 0.4 mg/dL (reference range 0.0 – 1.5). *Id.* at 57.

[3] ANA or antinuclear antibodies: antibodies directed against nuclear antigens; ones against a variety of different antigens are almost invariably found in systemic lupus erythematosus and are frequently found in rheumatoid arthritis, scleroderma (systemic sclerosis), Sjögren syndrome, and mixed connective tissue disease. Antinuclear antibodies may be detected by immunofluorescent staining. Serologic tests are also used to determine antibody titers against specific antigens. DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=56804 (last visited April 23, 2024) ("DORLAND'S").

[4] Anti-CCP antibody: an antibody against cyclic citrullinated peptide, seen almost exclusively in persons with rheumatoid arthritis and indicating a severe prognosis. DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=56787 (last visited April 23, 2024).

[5] Cryoglobulin: any of numerous immunoglobulins, not present in normal serum, that undergo reversible precipitation as serum cools. DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=11792 (last visited April 23, 2024).

Petitioner presented to Dr. Wilcox on August 26, 2015 with insomnia and gastrointestinal issues. Ex. 1 at 66-70. Petitioner reported that his insomnia began after his treatment with high-dose prednisone and since being weaned from it, the insomnia has not resolved. *Id.* at 66. Petitioner said he would wake up around 4 or 5am but would not be able to go back to sleep. *Id.* Petitioner was given Lunesta for his insomnia and Xifanan for his gastrointestinal issues. *Id.* at 70.

On September 16, 2015, Petitioner returned to Dr. Wilcox for pelvic pain. Ex. 1 at 78. Specifically, Petitioner noted suprapubic, perineal, and genital discomfort. *Id.* Regarding his sleep issues, Petitioner stated that his insomnia continued and he was able to sleep six hours with Lunesta. *Id*. Petitioner underwent a pelvic CT which was unremarkable, and a lumbar MRI which revealed spinal stenosis. *Id.* at 81. Dr. Wilcox recommended a urology consultation. *Id.*

Petitioner returned on September 28, 2015 for lower abdominal and bilateral inner thigh paresthesias. Ex. 1 at 83. In the HPI section, Dr. John Sislow noted that Petitioner still had mild bilateral wrist pain, unresolved lower abdominal fullness, inner thigh paresthesias, and deep urethral pain with minimal dysuria. *Id.* Dr. Wilcox also wrote "Adverse reaction to immunization" and "This may be a manifestation of his lumbar disc and nerve root disease" and recommended either a trial of gabapentin or a neurology consult. *Id.* Petitioner underwent another lumbar MRI which revealed "Congenitally short pedicles along with multifactorial degenerative changes. This is most significant at L4-5 with moderate central stenosis, moderate right neural foraminal canal stenosis, and mild left neural foraminal canal stenosis." *Id.* at 88.

On October 7, 2015, Petitioner visited Walla Walla Naturopathic where he was prescribed a multivitamin, vitamin C, adrenal stress herbs, and B stress comp. Ex. 6 at 1. In the HPI section, it was noted that Petitioner had pharyngitis and took Septra[6] which caused a rash to form on both his hands. *Id.* at 2. Petitioner also reported the left side of his neck locking, and his right pointer finger was inflamed the day after receiving a Tdap vaccine and he felt it felt like gout. *Id.*

Petitioner visited Dr. Martin Ross at the Healing Arts Partnership seeing on November 25, 2015. Ex. 4 at 18-22. Dr. Ross took a detailed history which was notable for wandering joint pain. *Id.* at 18. Dr. Ross noted, "His whole body is shaking and fasciculating. Weight loss and increased anxiety. His hands have improved [and] does not feel as much hum now has moved more proximal

[6] Septra: trademark for combination preparations of trimethoprim and sulfamethoxazole. DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=45431 (last accessed April 23, 2024). Trimethoprim: an antibacterial closely related to the antimalarial pyrimethamine, acting by inhibiting a step in bacterial folate biosynthesis and effective against various gram-negative and gram-positive bacteria; administered orally in the prophylaxis and treatment of urinary tract infections and the treatment of pneumocystis pneumonia. It is usually administered in combination with a sulfonamide because the two drugs markedly potentiate each other, and in such combination (e.g., co-trimoxazole) has additional uses including treatment of bronchitis, Shigellaenterocolitis, acute otitis media, and traveler's diarrhea. In certain countries, it is used alone as an antimalarial. DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=51090 (last accessed April 23, 2024). Sulfamethoxazole: a sulfonamide used as an antibacterial active against various gram-negative and gram-positive organisms, especially for the treatment of acute urinary tract infections, and as an antiprotozoal; administered orally, usually in combination with another agent such as trimethoprim. DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=47958 (last visited April 23, 2024).

now." *Id.* He underwent treatment for possible Lyme disease. *See generally* Ex. 4. *Id.* at 18. Petitioner mentioned that he began experiencing fatigue in his teen years but this worsened in the spring of 2015. *Id.*

Petitioner was seen by Dr. Wilcox on December 9, 2015 for follow up. Ex. 1 at 89-92. Dr. Wilcox informed Petitioner that if he was negative for Lyme disease, there was significant risk and harm with his unnecessary antibiotic therapy. *Id.* at 91. Petitioner was re-tested for Lyme disease on December 13, 2015 which returned negative. *Id.* at 93-94.

On December 10, 2015, Petitioner visited Dr. Adam Zierenberg, a physical medicine and rehabilitation specialist, for back, abdominal, and testicular pain that began after a reaction to a Tdap shot. Ex. 14 at 7. Petitioner informed Dr. Zierenberg that he had experienced multiple arthralgias that were severe and lasted several weeks; the worst pain at present was in the lower abdomen or pelvis. *Id.* Petitioner additionally reported that his symptoms had been worsening and rated his pain as moderate to severe. *Id.*

Petitioner visited Dr. Siew Min Wong, a gastroenterologist, at the Walla Walla Clinic on December 16, 2015 complaining of diarrhea and abdominal pain. Ex. 1 at 97-100. Dr. Wong noted Petitioner had a history of chronic diarrhea and abdominal pain for the past 10 years but his diarrhea reportedly became worse after he had a reaction to his Tdap vaccine. *Id.* at 97. Petitioner reported that, "the prednisone improved his weakness, but his fatigue, abdominal pain, diarrhea, and insomnia persist." *Id.* Dr. Wong prescribed Dulcolax and Ondansetron HCI. *Id.* at 108.

Later that month, on December 30, 2015, Petitioner returned to Dr. Wilcox for insomnia, pain, and other issues. Ex. 1 at 123. Dr. Wilcox noted that Belsomra, Petitioner's newest insomnia medication, worked briefly but became ineffective; he was next given extended release Ambien, which was only effective for four hours. *Id.* Regarding Petitioner's pain, Dr. Wilcox noted that he experienced generalized abdominal pain that would become so severe it would wake him up at night. *Id.* Dr. Wilcox assessed Petitioner with possible chronic fatigue syndrome but noted that his antibiotic regime with a naturopathic doctor complicates his treatment. *Id.* at 125. Petitioner was prescribed Seroquel for his insomnia and Xanax and oxycodone, to be used sparingly. *Id.* Petitioner also saw Dr. Wong on the same day for a follow-up after his colonoscopy, which was unremarkable. *Id.* at 127-39; *see also id.* at 117-18. Petitioner reported malaise, body aches, fatigue, and vague diffuse abdominal pain. *Id.* at 127. Under "Review of Systems," Dr. Wong noted joint pain, swelling or redness of joints and muscle pain. *Id.* at 128. Dr. Wong summarized stating, "patient with multiple somatic complaints, and pain out of proportion to physical exam, with some element of neuropathic pain." *Id.* at 139.

Petitioner went to the Providence St. Mary Medical Center emergency department on January 1, 2016, reporting abdominal pain and nausea. Ex. 14 at 12. Under HPI, it was noted that Petitioner had "significant insomnia for the last 2-3 weeks" with facial and muscle twitching, along with two weeks of intermittent abdominal pain. *Id.* Petitioner reported that "his syndrome started when he was given a tetanus injection approximately 6 months ago." *Id.* He was referred to the University of Washington neurology department. *Id.* at 16-17.

The next day, on January 2, 2016, Petitioner visited Adventist Health Walla Walla General Hospital complaining of jaw tightness and teeth grinding. Ex. 1 at 141. Petitioner stated he could only sleep two hours at a time, and his current problem arose at 4:00am; he came to Walla Walla General because St. Mary's did not see him in a timely fashion. *Id.* Petitioner reported that "he's been diagnosed as having Lyme's disease. Lab test originally was negative [at a] FDA approved lab but positive at a specialized Lyme's disease testing facility." *Id.* Petitioner was discharged when his mouth and jaw moved normally. *Id.* at 143.

Petitioner had a follow-up with Dr. Wilcox on January 29, 2016 for his insomnia, specifically requesting a refill of Ambien. Ex. 1 at 159. Dr. Wilcox noted

> Since his last visit, he was apparently evaluated by Dr. Wilkinson in Yakima and told that he had "a traumatic brain injury and inflamed nervous system" related to his reaction to tetanus vaccination last summer. He is being treated with intravenous vitamin C. Dr. Wilkins also increased his Xanax… Dr. Wilkinson apparently also recommend the extremely high doses of melatonin. Apparently additional laboratory testing was performed, but unfortunately we have not received any of those results or any chart notes…. His Xanax [] works very well, calming his abdominal symptoms, testicular pain, and other symptoms.
>
> The patient has apparently quit his job… moved into the house of his mother-in-law.
>
> Apparently his antibiotic regimen has been switched for treatment of "Lyme Disease" despite repeat normal laboratory assessments.

Id. Dr. Wilcox informed Petitioner that he was not comfortable increasing his dose of Ambien as it exceeds the recommended dosing, especially in combination with his high dose of Xanax. *Id.* at 162. Dr. Wilcox also stated:

> The character of his symptoms and his keen response to Xanax are suggestive of an anxiety disorder. This may be causing or exacerbating his multitude of complex symptoms including his insomnia. I recommended a psychology evaluation and cognitive therapy, which he declined.
>
> The patient's case is obviously compromised by his many providers independently prescribing therapies without sharing information with his PCP. He is taking no less than 10 nutritional supplements of dubious benefit and unclear side effects.

Id. Petitioner was scheduled for a neurology consultation. *Id.*

Neurologist Dr. John Chaplin examined Petitioner on February 9, 2016. Ex. 1 at 165-67. Petitioner reported that his primary symptom was a buzzing/vibrating sensation throughout his body, which causes his inability to sleep. *Id.* at 165. Petitioner's physical examination was normal. *Id.* at 166. Dr. Chaplin's impression was:

> Michael reports chronic pain but when I ask him where he has pain he cannot even answer this question. Clearly he has a large component of anxiety and somatization which I believe is his primary problem. I see no evidence to support a diagnosis of Lyme disease and he certainly does not have neurologic manifestations of Lyme disease such [as] polyradiculopathy or peripheral neuropathy and his neurologic exam today is pristinely normal…. One of his alternative medicine providers in Tri-Cities has told he has an "inflamed brain" and I see no evidence to support this contention. Mike clearly prefers an alternative medicine pathway in pursuit of a diagnosis and treatment. However, he is exposing himself to serious risk and potentially fatal risk with his chronic exposure to antibiotics…. This puts him at great risk to significant harm to his gut microbiome.

Id.

On February 15, 2016, Petitioner was admitted to Swedish Medical Center in Seattle for jaundice, elevated transaminase levels, and "medication induced liver injury." Ex. 7 at 4. Petitioner's medical history upon admission was that he "has felt unwell since March 2015" when he felt he had the flu and "yellow tongue." *Id.* at 15. After receiving the Tdap vaccine, he awoke with left cervical joint heat and could not move. *Id.* The nurse recorded Petitioner's symptoms and numerous medications from the past few months. *Id.* Petitioner was seen by Dr. Muktar, a hepatologist, who ran a full hepatic workup on Petitioner to diagnose the elevated transaminase and jaundice. *Id.* at 19. Petitioner was discharged on February 18, 2016 with instruction to stop all supplements and antibiotics. *Id.* at 6-7. It was recommended that Petitioner see a rheumatologist. *Id.* at 6.

On February 29, 2016, Petitioner traveled to Seattle to have a consultation with Dr. Anthony Krajcer, a rheumatologist at the Polyclinic. Ex. 5 at 2. Petitioner stated he had "gout-like symptoms" in his joints, which were helped by prednisone but he has a "general unwell feeling." *Id.* A thorough medical history was taken noting "things began to go awry in March 2015." *Id.* After vaccination, Petitioner had neck pain, right MP joint pain and deltoid discomfort, with migratory arthralgias, some visible swelling/stiffness which [was] localized to wrists, shoulders, knees, and ankles. *Id.* Regarding his present condition, it was also noted that "[Petitioner]'s not had any concerning musculoskeletal symptoms aside from some low back stiffness and his primary concern at this time are some vague paresthesias of the upper more so than the lower extremities also hypersensitivity/discomfort in the perineal area/scrotal." *Id.* at 3. On physical exam, Petitioner was noted to have localized tenderness to palpation in his peripheral joints, shoulders, and knees. *Id.* at 5. Dr. Krajcer's impression was systemic inflammatory response syndrome ("SIRS") subsequent to a vaccination with reported migratory arthritis and spondylitis symptoms in the neck. *Id.* at 11. Dr. Krajcer added there was "No clear unifying rheumatologic explanation [ ]. No evident vasculitis or history that is suggestive of this. Most musculoskeletal migratory inflammatory symptoms have resolved over the summer subsequent to steroid course. (Remote consideration for reactive arthritis/spondyloarthropathy)" and "I see no indications for any anti-inflammatory/immunosuppressive treatment." *Id.* Dr. Krajcer subsequently emailed Petitioner a message on March 11, 2016 suggesting that his SIRS "may gradually burn out" and "[t]he Tdap vaccination is on your allergy list here and should be in any other healthcare setting." *Id.* at 20.

Petitioner visited Dr. Daniel Drozd for an infectious diseases consultation at the Polyclinic, pertaining to his "Lyme [disease] serologies" in March 17, 2016. Ex. 5 at 22. Dr. Drozd noted "[Petitioner] has had a rather unbelievable and unfortunate course over the past year which at least temporally seem[s] to have started with a reaction following a Tdap vaccine," further adding a review of Petitioner's lab work was not indicative of Lyme disease, stating "I think unfortunately that he has suffered a number of consequences, most significantly his acute livery injury that resulted from his exposure to treatment directed at [Lyme] disease." *Id.* at 30.

The next day, on March 18, 2016, Petitioner was seen by Dr. Benduan Yang, a neurologist at the Polyclinic. Ex. 5 at 34-37. Dr. Yang noted, "Patient continues to have remarkable weakness of the arms and legs, paresthesia, [and] muscle fasciculations," and Petitioner denied any significant cognitive issues. *Id.* at 35. Dr. Yang's impression was "probably transverse myelitis" after receiving tetanus booster vaccine in May 2015 but "was not confirmed by extensive imaging and CSF study." *Id.* at 36. A possible explanation was that Petitioner's imaging was taken too soon but Dr. Yang added, "This was probably induced by vaccine." *Id.* Dr. Yang recommended a repeated cervical spine MRI back in Walla Walla and IV steroids for residual inflammatory changes. *Id.* at 37.

On October 31, 2016, Petitioner returned to his PCP, Dr. Wilcox for a follow-up. Ex. 1 at 195-97. Petitioner informed Dr. Wilcox of his traverse myelitis diagnosis. *Id.* at 195. Dr. Wilcox recommended additional CT scans to make sure his liver was still recovering well. *Id.* at 196.

Dr. Wilcox signed vaccine exemptions for Petitioner for the annual flu and COVID vaccines. Ex. 11 at 23, Ex. 54 at 26.

No other medical records were filed that pertain to Petitioner's alleged injury.

III. Petitioner's Testimony

Petitioner testified at the May 18, 2022 entitlement hearing. Mr. Schwarz works as a physical therapist. Tr. at 6. Petitioner received a Tdap vaccine on May 20, 2015 during his 40 year-old wellness check due to his work in the health care field. *Id.* at 7. Petitioner did not have an immediate reaction to the vaccine but a few days later, on a Friday, he woke up with neck pain on one side of his neck; he believed that he just slept poorly and went on with his day until the pain spread across his neck. *Id.* at 8-9. Petitioner cancelled his patients for the day and went to the Adventist Health emergency room after calling his doctor, who told him to do so. *Id.* at 9. At the emergency room, the pain had spread from his neck to his shoulder, jaw, and chest. *Id*. Petitioner underwent a lumbar puncture during this visit which was memorable because it was so painful. *Id.* He was discharged with a diagnosis of neck pain. *Id.* at 10.

The next day, Petitioner felt his pain getting worse and went to the other emergency room in Walla Walla, Washington, St. Mary's Providence. Tr. at 10. He underwent more tests and was told by the doctors that he was experiencing a reaction to the vaccine he had just received. *Id.*

Petitioner returned to his PCP, Dr. Wilcox later in May 2015. Tr. at 11. Dr. Wilcox prescribed him with low dose prednisone, which helped ease his pain but was "still not cutting it."

Id. He recalled attending his son's eighth grade graduation and not being able to get up from his chair because his hips locked up. He had to be lifted by his brother and good friend in order to leave because his legs were not working. *Id.* at 11-12.

Petitioner described his pain as a 20 out of 10 in his joints and roaming from his upper body to his lower body. Tr. at 12. Dr. Wilcox attempted to taper Petitioner off of prednisone but his symptoms got worse. *Id.* Dr. Wilcox then prescribed him with high dose prednisone. *Id.* Petitioner finally felt improvement; he could walk and move his joints, but not all of his pain and stiffness were gone. *Id.* at 13.

Petitioner was referred to Dr. Moore for another opinion. Tr. at 13. Dr. Moore did not change his medications but ran more tests, and believed Petitioner's condition was caused by his vaccination. *Id.*

Petitioner recalled that the summer months were still difficult. Petitioner owned his own business so he had to do some work to pay the bills. Tr. at 14. The pain was affecting his ability to sleep and he developed insomnia. *Id.* Because of his condition, his family went on their annual summer trip without him. *Id.* at 15. Dr. Wilcox again tried to taper him from prednisone which Petitioner recalled was a very long process. *Id.* Petitioner continued to have insomnia, fatigue, and joint pain in his upper extremities. *Id.* at 15-16.

Petitioner worked until about December when he could not perform anymore. Tr. at 16. His work days would get shorter and shorter because his pain would be unbearable. *Id.* He gradually had to take whole days off to recover. *Id.* Petitioner stated that his wrists would be red and swollen, his hands would get puffy, and this affected his ability to work. *Id.* at 17. Beyond the pain, Petitioner also experienced brain fog. *Id.*

Because he was desperate to get treatment and answers, Petitioner began to seeing naturopathic doctors. Tr. at 18. One doctor told him he had Lyme's disease and gave him antibiotics, which caused liver damage. *Id.* at 19. Petitioner was recommended to see a rheumatologist, Dr. Krajcer, at the Polyclinic. *Id.* Petitioner had "very good, fond memories" of the Polyclinic because the doctor did "full-on testing." *Id.* Dr. Krajcer told him this was a vaccine reaction and that in 26 months "it burns itself out." *Id.* at 20. The doctor did not change his treatment regimen. *Id.*

In early 2016, Petitioner recalled that January and February were his worst; he was airlifted to Swedish Hospital in Seattle for treatment. Tr. at 21-22. Petitioner called his pastor to tell him "you're going to do my eulogy because… I never felt anything like it." *Id.* at 21. He made videos to kids and a video to his brother to tell him "how I wanted everything to go," "because I thought… that was it." *Id.* Petitioner was not able to work and moved in with his mother-in-law because she was a retired nurse. *Id.* Petitioner's symptoms included pain, fatigue, insomnia, joint pain, and swelling. *Id.* In March 2016, Petitioner was referred to Dr. Yang, a neurologist, at Swedish Hospital because it was a bigger facility and could provide better treatment options. *Id.* at 22-23. Dr. Yang similarly told Petitioner that his symptoms were part of the reaction to his Tdap vaccine. *Id.*

Petitioner's office manager informed him she was getting a knee replacement in July 2016 and wanted him to do her PT. Tr. at 24-25. As a result, Petitioner began setting small tasks for himself to build up his endurance; his office manager was his first patient, whom he treated twice per week. *Id.* at 25. He slowly added more patients and was working two full days each week. *Id.* The more he used his hands and wrists for work, the more inflamed they would become. *Id.* at 26. By 2017, Petitioner was able to get back to working four days per week but was not able to work more. *Id.* Before his injury, Petitioner was very active outdoors; he was a snowboard instructor and enjoyed hiking and camping. *Id.* at 27. Petitioner testified that he was able to go snowboarding twice on his annual pass this past year. *Id.*

Petitioner now works as a director and sees about five patients per day, which works well for him because that limits the work with his hands, wrists, and shoulders. Tr. at 28. Prior to his injury, he was growing a clinic and worked long hours and felt that the growth was limitless. *Id.* at 29. Petitioner reported that his symptoms today include insomnia, and wrist and hand pain if he does too much activity. *Id.* Doctors have told Petitioner not to receive another Tdap vaccination. *Id.* at 30.

IV. Expert Opinions and Qualifications

A. Dr. Yuval Shafrir

Dr. Shafrir authored one expert report. Ex. 16 (hereinafter "Shafrir Rep.") and also testified at the entitlement hearing.

This case is somewhat unusual in that I did not ultimately rely on Dr. Shafrir's opinion with respect to Petitioner's correct diagnosis. As discussed in detail below, I find the opinions of Petitioner's treating physicians to be more persuasive in this regard. I have, however, summarized Dr. Shafrir's expert report and hearing testimony to lend context to my ruling.

1. Qualifications

Dr. Shafrir attended medical school at the Sackler School of Medicine at Tel Aviv University. Ex. 17 (hereinafter "Shafrir CV") at 1. Dr. Shafrir completed a rotating internship and a pediatrics residency at North Shore University Hospital, which is affiliated with Cornell University. *Id.* Dr. Shafrir also completed a pediatric neurology residency and fellowship at Washington University Medical Center, and a pediatric neurophysiology and epileptology fellowship at Miami Children's Hospital. *Id.* at 2. Dr. Shafrir is board certified in pediatrics, neurology, and clinical neurophysiology. *Id.* Dr. Shafrir served as a major in the U.S. Army Medical Department at Walter Reed Army Medical Center. *Id.* Dr. Shafrir worked as a pediatric neurologist at a number of institutions, and is currently at Sinai Hospital. *Id.* at 3. Dr. Shafrir primarily treats patients with PANS/PANDAS. Tr. at 83-84. I recognized Dr. Shafrir as an expert in neurology. *Id.* at 34-35.

2. Expert Report

Dr. Shafrir began his report by conducting an extensive summary of Petitioner's medical

history. Shafrir Rep. at 1-39. He noted that although Petitioner experienced recurrent episodes of sore throat, sinusitis, cold symptoms, and congestion, it is unlikely these complaints caused any of Petitioner's current problems as he had these symptoms for years before vaccination and they did not result in the problems Petitioner experienced post-vaccination. Shafrir Rep. at 39. Dr. Shafrir noted that Petitioner's history of sore throat, sinusitis, cold symptoms, and congestion does suggest some level of innate immune dysregulation. *Id.*

Dr. Shafrir acknowledged that "[n]o unified diagnosis was ever reached." Shafrir Rep. at 40. He pointed out that all of Petitioner's treating physicians agreed that "his initial symptomology was a result of the vaccination." *Id.* Dr. Shafrir stated that these opinions were reinforced by Petitioner's positive response to steroid treatment and his negative response when steroids were withdrawn. *Id.*

Dr. Shafrir then enumerated the various diagnoses listed in Petitioner's medical records. Dr. Shafrir noted that although Dr. Yang diagnosed Petitioner with transverse myelitis ("TM"), Dr. Yang was "speculating" based on Petitioner's medical history. Shafrir Rep. at 40. Dr. Shafrir acknowledged that "[w]e do not have solid support for this diagnosis in the contemporaneous medical records." *Id.* Dr. Shafrir stated that Dr. Wilcox diagnosed Petitioner with reactive generalized migratory polyarthralgia, and Dr. Krajcer diagnosed him with systemic inflammatory response syndrome (SIRS). *Id.*

According to Dr. Shafrir, the unifying diagnosis for Petitioner's complex medical presentation is chronic fatigue syndrome, "probably a specific sub type – aluminum adjuvant induced macrophagic myofasc[i]itis." Shafrir Rep. at 40. He then stated that the four diagnoses (TM, SIRS, reactive generalized migratory polyarthralgia, and CFS) "were present at one time or another, reflecting different aspects of the excessive systemic inflammation induced by the vaccine." *Id.*

Dr. Shafrir then discussed each of the four "manifestations of Mr. Schwarz's condition." Shafrir Rep. at 40. He began with transverse myelitis. Dr. Shafrir noted that the correlation between vaccines and TM has been well known for many years. *Id.*

Dr. Shafrir next discussed SIRS. He opined that Petitioner's medical records do not clearly indicate that he met the diagnostic criteria for this condition. However, Dr. Shafrir stated that Petitioner "definitely had [a] less severe but extensive inflammatory reaction to the vaccine." Shafrir Rep. at 41. Dr. Shafrir highlighted that cytokine levels increase rapidly after vaccination. *Id.* at 42.

Dr. Shafrir next discussed reactive arthritis. He opined as follows: "Reactive arthritis is well described in the literature after several vaccines, including components of the DTP vaccination." Shafrir Rep. at 42. He noted that reactive arthritis generally occurs within one or two days of vaccination. *Id.*

Dr. Shafrir stated that brachial neuritis was another "component[] of the exaggerated inflammatory response in Mr. Schwarz." Shafrir Rep. at 42. He noted that Petitioner's medical records noted decreased reflexes in the upper extremities associated with pain and weakness in

both arms. *Id.* (citing Ex. 1 at 33). Dr. Shafrir opined that "[t]his temporary abnormality in neurological examination[] may fit the criteria for brachial neuritis as stated in the vaccine injury table." Shafrir Rep. at 42. Dr. Shafrir noted that if Petitioner did have brachial neuritis, this diagnosis "cannot provide a full explanation [for] Mr. Schwarz's severe disability." *Id.* at 43.

Dr. Shafrir next turned to chronic fatigue syndrome. He opined that Petitioner's "presentation[] fully fit the new IOM definition for myalgic encephalomyelitis/chronic fatigue syndrome from 2015." Shafrir Rep. at 43. Dr. Shafrir opined that the diagnosis of chronic fatigue syndrome is the diagnosis "most supported by the medical records." Shafrir Rep. at 45. He stated that each of the three *Althen* prongs have been met. *Id.* In discussing *Althen* prong one, Dr. Shafrir opined that "Mr. Schwarz's symptoms and complaints can be explained on the basis of immune reaction causing chronic fatigue syndrome." *Id.* He noted that Petitioner's "symptoms persisted through the activity of the adaptive immune system." *Id.* The mechanisms that caused the persistence of symptoms included "molecular mimicry, bystander activation, epitope[] spreading and maybe even polyclonal activation." *Id.*

With respect to *Althen* prong two, Dr. Shafrir opined as follows:

> The vaccination with Adacel produced a dramatic auto inflammatory reaction which was initially mediated by the innate immune system for inflammatory cytokines (known to be triggered by the Adacel antigenic components and aluminum adjuvant), producing [an] initial local reaction which was rapidly followed by more systemic manifestations, affecting multiple body systems.

Shafrir Rep. at 45.

Dr. Shafrir opined that Petitioner's symptoms began two days after vaccination. Shafrir Rep. at 45. He attributed the rapid onset of Petitioner's disease to a memory response due to the fact that he had received previous Tdap vaccinations in the past, as well as the activation of the innate immune system through the production of cytokines. *Id.*

3. Testimony

Dr. Shafrir began his testimony by interpreting a number of Petitioner's medical records. Dr. Shafrir discussed Petitioner's visit with Dr. Wilcox on July 9, 2015 and the lab tests that were run, which returned negative. Tr. at 42-43. Dr. Shafrir noted that reactive arthritis could only be diagnosed upon physical examination, and there were no diagnostic tests for this condition. *Id.* at 42.

Petitioner's appointment with Dr. Krajcer resulted in a new differential diagnosis of SIRS, however Dr. Shafrir does not believe that Petitioner has SIRS because "he does not meet the criteria, and there's no place in which he did meet the criteria, but [Dr. Krajcer] tries to make [ ] a framework to [ ] understanding it." Tr. at 52-53. Dr. Shafrir elaborates that, "I think that Dr. Krajcer is trying to find a way to explain so many symptoms occurring in the same person in response to the same provocation." *Id.* at 53.

Dr. Shafrir discussed Petitioner's visit with Dr. Yang. Tr. at 59-60. Dr. Shafrir testified Dr. Yang's diagnosis did not indicate Petitioner suffered from that condition at the time of the appointment; but instead, Dr. Yang likely gave Petitioner a diagnosis "that could have explained his symptoms" from 2015. *Id.* at 59-60.

Regarding the diagnoses that Petitioner received, Dr. Shafrir opined that he had reactive arthritis and "there is no question about it." Tr. at 63. In the diagnostic criteria submitted by Dr. Shafrir, the condition could have a quick recovery but could also last for months and require prolonged treatment. *Id.* Reactive arthritis is associated with "sky-high" C-reactive protein levels. *Id.* Dr. Shafrir did testify that some of Petitioner's symptoms, such as his persistent paresthesias, or sensory issues, could not be explained by reactive arthritis. *Id.* at 63-64.

Dr. Shafrir opined that Petitioner also suffered from chronic fatigue syndrome. Tr. at 64-65. Although Petitioner did not experience all symptoms associated with CFS, such a cognitive dysfunction or postural intolerance, he did experience poor sleep, GI symptoms, and irritable bowel. *Id.* Dr. Shafrir clarified that while Petitioner did not have unrefreshing sleep (which is part of the CFS diagnostic criteria), he had a sleep disorder which is part of the syndrome. *Id.* at 70. Dr. Shafrir opined that Petitioner's chronic fatigue syndrome was "definitely [an] indirect result of the vaccination." *Id.* at 68. Dr. Shafrir admitted, "in the context of the Vaccine Program, we cannot establish temporal relationship between the onset of CFS and the vaccination." *Id*. at 83.

Dr. Shafrir cited to the Kesiktas article and Maillefert article, two case report articles involving patients who developed arthritis after vaccination. Tr. at 71-73; Kesiktas et al., *A Case of Reactive Arthritis Developed After Tetanus Vaccine*, 7 IKSST DERG 3 147-49 (2015) (filed as Ex. 43); Maillefert et al., *Arthritis following combined vaccine against diphtheria, poliomyelitis, and tetanus toxoid*, 18 CLINICAL AND EXPERIMENTAL RHEUMATOLOGY 255-56 (2000) (filed as Ex. 44).

Regarding a causal mechanism, Dr. Shafrir stated that a reaction to the Tdap vaccine can occur within 72 hours, as detailed in medical literature. Tr. at 74. He cited to the Agmon-Levin article to explain the mechanism by which the Tdap vaccine caused Petitioner's reactive arthritis. *Id.* at 74-75; Agmon-Levin et al., *Vaccines and autoimmunity*, 5 NATURE REVIEWS RHEUMATOLOGY 648-52 (2009) (filed as Ex. 53). Dr. Shafrir also mentioned cytokines and the innate immune system are involved to cause these extremely rare occurrences. *Id.* at 75. Dr. Shafrir highlighted Dr. Krajcer's note that this was likely a cytokine reaction from the vaccine. *Id.* at 77.

Dr. Shafrir testified that Petitioner suffered from a systemic illness; he was bedridden for six to eight weeks and this cannot be explained by just reactive arthritis. Tr. at 84. Dr. Shafrir confirmed that Dr. Wilcox used the term "generalized migratory arthralgia" rather than reactive arthritis, but stated those terms were interchangeable. *Id.* at 87, 89-90. Dr. Shafrir testified that although patients with reactive arthritis generally had an asymmetric presentation, bilateral symptoms does not rule out the diagnosis, as laid out in the Kesiktas article. *Id*. at 91; *see also* Kesiktas at 1. Dr. Shafrir highlighted the Kaul paper as proof of a challenge-rechallenge reaction; a patient with Reiter's syndrome, a form of reactive arthritis, had a flare up after receiving a tetanus vaccination. *Id.* at 95; Kaul et al., *Recurrence of reactive arthritis after a booster dose of tetanus toxoid*, ANN RHEUM DIS. 185 (2002) (filed as Ex. 46). According to Dr. Shafrir, this demonstrates

an association between reactive arthritis and the Tdap vaccine, even if it does not rise to level to "establish a causal relationship." *Id.*

Dr. Shafrir reiterated that Petitioner experienced many of the symptoms associated with chronic fatigue syndrome, such as an irritable bowel, muscle pain, genitourinary impairment, sore throat, and sensitivity to external stimuli; but he did not have orthostatic intolerance or cognitive impairment. Tr. at 96-97. Dr. Shafrir emphasized that many of the symptoms on the Adacel package insert overlapped with CFS, such as body aches, muscle weakness, sore and swollen joints. *Id.* at 99-100.

Dr. Shafrir admitted that beyond Petitioner's testimony earlier in the entitlement hearing, there was "no objective evidence in the record that he ha[d] ongoing arthritis" as of March 2016. Tr. at 104; *see also* Ex. 5 at 11. Dr. Shafrir opined that despite this record, he believed Petitioner was still experiencing musculoskeletal issues, just not to the same degree as the summer of 2015. *Id.* at 106. Dr. Shafrir stated that he believed Petitioner's reactive arthritis lasted at least four months and possibly up until his liver failure, which was six months after vaccination. *Id.* at 108.

Regarding brachial neuritis, Dr. Shafrir opined that there is some evidence to support this diagnosis as Petitioner had a difference in his reflexes and had migratory weakness in his arms with residual paresthesias. Tr. at 110. Dr. Shafrir also noted that Petitioner's vibration sensation had a term, pallesthesia. *Id.* Given his other symptoms, Dr. Shafrir conceded there is not strong evidence to support the diagnosis. *Id.* Dr. Shafrir reiterated that he believed Petitioner experienced "reactive arthritis plus plus," or reactive arthritis with other symptoms which were also autoinflammatory in nature. *Id.* at 111.

Dr. Shafrir described how the Tdap vaccine indirectly caused Petitioner's chronic fatigue syndrome. He stated that the persistent elevation of cytokines can cause weight loss, cachexia,[7] fatigue, lack of energy, and depression. Tr. at 112. The Agmon-Levin paper provided mechanisms for how an antibody-mediated reaction persisted in Petitioner's immune disease. *Id.* at 112-13. Dr. Shafrir opined that Petitioner's CFS started "the moment that his acute symptoms related to his "arthritis plus plus" were no longer explaining his inability to function," or four or five months after the onset of his symptoms. *Id.* at 113. Dr. Shafrir testified that Petitioner did not have chronic fatigue syndrome before his vaccination. *Id.* at 114.

B. Dr. Michael Wilson

Dr. Wilson authored one expert report, Ex. A (hereinafter "Wilson Rep.") and also testified at the entitlement hearing.

1. Qualifications

Dr. Wilson received a B.A from the University of Chicago and an M.D. from the University of California, San Francisco (UCSF) School of Medicine. Ex. B (hereinafter "Wilson CV") at 1.

[7] Cachexia: a profound and marked state of constitutional disorder; general ill health and malnutrition. DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=7417 (last visited April 23, 2024).

Dr. Wilson completed his residency in neurology at Harvard Neurology Residency Program and a fellowship in neuro-infectious disease at Massachusetts General Hospital. *Id.* Dr. Wilson subsequently completed a post-doctoral fellowship in neurovirology at Boston University and a separate post-doctoral fellowship in metagenomics at UCSF. *Id.* Dr. Wilson is board certified in neurology. *Id.* Dr. Wilson teaches at the UCSF School of Medicine as an associate professor of neurology. *Id.* at 2. Dr. Wilson serves as an ad hoc reviewer on a number of publications including Neurology, JAMA Neurology, the New England Journal of Medicine, International Journal of Infectious Diseases, and Lancet Infectious Diseases. *Id.* at 5. Dr. Wilson has published at least 57 peer-reviewed articles and 11 book chapters. *Id.* at 25-31. Dr. Wilson is the principal investigator on five different NIH grants. Tr. at 122, Wilson CV at 20-22. I recognized Dr. Wilson as an expert in neuroimmunology. Tr. at 125.

2. Expert Report

In his expert report, Dr. Wilson addressed Dr. Shafrir's expert report where he opined that Petitioner developed CFS, TM, reactive generalized polyarthalgias/SIRS, and brachial neuritis as a result of his Tdap vaccine. Wilson Rep. at 5.

Dr. Wilson first discussed transverse myelitis. He agreed with Dr. Shafrir that "we do not have solid support for this diagnosis in the contemporaneous medical records." Wilson Rep. at 5 (citing Shafrir Rep. at 40). Dr. Wilson opined that Petitioner "lacked many of the objective findings of transverse myelitis." *Id.* Specifically, Dr. Wilson noted that Petitioner had a normal cervical spine MRI both at the time his symptoms began and nearly one year later. *Id.* Dr. Wilson stated that although it is possible one would not see a spinal cord abnormality at the very beginning of an episode of TM, "the inability to also see a scar on the cervical spine MRI the following year makes it even less likely that there was ever an inflammatory lesion (or any other kind of injury) in the spinal cord." *Id.* He opined further on this issue, noting that he would expect to see "a scar manifest as a hyperintensity on the T2-weighted MRI sequence and/or as myelomalacia (i.e., thinning of the spinal cord) as a result of chronic nerve damage." *Id.* Dr. Wilson further noted that Petitioner had no inflammation in the CSF. *Id.* In addition, "his EMG/NCS identified no muscle or nerve abnormality that could be localized back to the nerve root or spinal cord." *Id.* All these factors suggest that Petitioner did not have TM. *Id.*

Dr. Wilson next addressed Chronic Fatigue Syndrome. Dr. Wilson noted that Petitioner had been experiencing chronic fatigue since he had mono as a teenager. Wilson Rep. at 5. Additionally, he had a ten plus year history of chronic abdominal pain and loose stools, which worsened in the months after vaccination as a result of a drug-induced liver injury. *Id.* Dr. Wilson opined: "Given that he already had these chronic symptoms before the Tdap vaccination, it is not clear why a vaccine-induced reaction needs to be invoked to explain why he continues to have these symptoms." *Id.* Dr. Wilson further noted that a diagnosis of macrophagic myofasciitis requires a muscle biopsy, which Petitioner did not have. *Id.* at 5-6.

Dr. Wilson next discussed Petitioner's proposed diagnosis of migratory polyarthralgias and Systemic Inflammatory Response Syndrome (SIRS). Dr. Wilson noted that systemic inflammation with arthralgias and myalgias can occur after Tdap vaccination, however, this type of reaction lasts

for a period of days. Wilson Rep. at 6. To receive a diagnosis of SIRS, the following criteria must be met:

> (1) a body temperature greater than 38°C or less than 36°C; (2) a heart rate greater than 90 beats per minute; (3) tachypnea, manifested by a respiratory rate greater than 20 breaths per minute, or hyperventilation, as indicated by a PaCO2 of less than 32 mm Hg; and (4) an alteration in the white blood cell count, such as a count greater than 12,000/ cu mm, a count less than 4,000/cu mm, or the presence of more than 10 percent immature neutrophils ("bands").

Id. (citing Bone et al., *Definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis*, The ACCP/SCCM Consensus Conference Committee, American College of Chest Physicians/Society of Critical Care Medicine, 101 CHEST 6, 1644-55 (1992) (filed as Ex. F)). Dr. Wilson opined that Petitioner did not meet these criteria. Wilson Rep. at 6. Dr. Wilson noted that Petitioner's repeat C-reactive protein two months after vaccination was normal and his arthralgias had improved, "indicating that any inflammatory condition petitioner suffered from had passed." *Id.*

Dr. Wilson next discussed Dr. Shafrir's proposed diagnosis of brachial neuritis. Dr. Wilson opined that "it is far from clear that this diagnosis is consistent with Mr. Schwarz's presentation." Wilson Rep. at 6. Dr. Wilson noted that Petitioner's EMG/NCS "showed no evidence of prior damage to the brachial plexus on either side." *Id.* Further, Petitioner never had "individual upper extremity muscle testing that suggested that muscle groups that localize to a particular spinal cord level or region of the brachial plexus were weak. Rather, the notes suggest that he was generally weak in the arms (with no grading of the severity of the weakness)." *Id.* Additionally, Petitioner had intact sensory testing, which, according to Dr. Wilson, "makes it very difficult to contend that his condition was due to brachial neuritis." *Id.* Finally, Dr. Wilson opined that brachial neuritis is a diagnosis of exclusion, yet Dr. Shafrir has proposed other conditions that explain Petitioner's condition. *Id.*

Ultimately, Dr. Wilson opined that Petitioner had "some degree of systemic inflammation in the immediate aftermath of his vaccination that caused diffuse joint pains and stiffness." Wilson Rep. at 7. However, he stated that these symptoms resolved soon after vaccination. *Id.* He further opined that Petitioner had fatigue and chronic abdominal complaints which preceded vaccination. *Id.*

3. Testimony

Dr. Wilson testified that he did not believe Petitioner suffered from transverse myelitis. Tr. at 126-28. Dr. Wilson agreed with Dr. Shafrir that Petitioner did not suffer from brachial neuritis. *Id.* at 129-30. Finally, Dr. Wilson stated he did not believe that Petitioner suffered from SIRS. *Id.* at 130.

Dr. Wilson next addressed Petitioner's other diagnoses. He stated that CFS was a syndrome, or a constellation of symptoms. Tr. at 130-31. Dr. Wilson believed there was not enough information to diagnose Petitioner with CFS pursuant to the IOM diagnostic criteria and that it

was clear in the record that Petitioner experienced chronic fatigue many years before vaccination. *Id.* at 130-31. Dr. Wilson stated he did not address macrophagic myofasciitis because Petitioner never had a biopsy. *Id.* at 133-34.

Dr. Wilson addressed the differences between inflammatory diseases, autoinflammation, and autoimmunity. An autoinflammatory disease is defined as "a group of genetic diseases described in family, in which a number of the family members, have a gene mutation that's critical for innate immunity." Tr. at 134-35. One such example is cryopyrin-associated periodic syndrome (CAPS), where these family members experience recurrent inflammation in organ systems; but more commonly known conditions are rheumatoid arthritis, multiple sclerosis, and lupus. *Id.* at 135. Dr. Wilson opined that Petitioner experienced an acute inflammatory reaction after vaccination. *Id.* at 136. Petitioner experienced the hallmarks of temporally linked diffuse muscle pain, which was steroid responsive and systemic markers of inflammation (high C-reactive protein and elevated white blood cell count), which "are not uncommon kinds of symptoms and reactions to have to vaccinations generally." *Id.* Dr. Wilson testified that Petitioner experienced a self-limited reaction or that his myalgias and arthralgias subsided over the weeks with prednisone. *Id.* at 136-37. This was confirmed with follow-up lab tests, which showed normal inflammatory markers after time along with improved symptomology. *Id.* at 137-39. Dr. Wilson stated that rheumatologists are experts of musculoskeletal and joint exams, so there still could be compartmentalized inflammation that would not show up in blood work but show up on examination. *Id.* at 139. Petitioner never underwent an arthrocentesis to look for joint inflammation, which would document his inflammation. *Id.* at 140.

Dr. Wilson defined arthralgia as pain in joints, comparable to myalgia which is muscle pain. Tr. at 140. Just as a myelitis, or inflammation of the spinal cord, falls under a myelopathy, or problem with the spinal cord; arthritis falls under arthralgia because joint inflammation will include joint pain. *Id.* at 140-41. The medical records demonstrate Petitioner had polyarthralgias and polymyalgias, but Dr. Wilson does not believe those were caused by acute or chronic inflammation of the joints, or arthritis. *Id.* at 141.

Regarding Dr. Shafrir's causation theory, Dr. Wilson understood it to be that Petitioner experienced an acute reactive arthritis that was triggered by vaccination; immunosuppressive therapies helped but inflammation lingered past the acute phase and led to a more chronic fatigue picture, complicated by Petitioner's many prescriptions by various providers. Tr. at 141-42. Dr. Wilson opined that he did not believe Dr. Shafrir had explained the connection between the joint and muscle pain with Petitioner's fatigue symptoms, especially because Petitioner had sleep issues after a viral infection as a teenager, well before vaccination. *Id.* at 142. Dr. Wilson noted that Petitioner had been experiencing ongoing weight loss as of his emergency room visit on May 23, 2015. *Id.* at 144; *see also* Ex. 1 at 31.

Dr. Wilson testified that Petitioner's misuse of prescription medication was a leading suspect as the cause of Petitioner's GI issues, such as loose stool, abdominal bloating, and liver failure. Tr. at 145. Petitioner's consumption of supplements did not help as the FDA does not regulate the supplement industry. *Id.* Many supplements contain adulterants; there may be value from taking supplements, but the quality concerns may override benefits. *Id.* at 146. Petitioner took enough medications and supplements to suffer from liver damage, which can cause systemic

unwellness, and the poison from the liver damage on top of his health issues can manifest as "unwell symptoms." *Id.*

Dr. Wilson agreed that the arthralgias Petitioner experienced on July 29, 2015 were from his vaccination. *Id.* at 152; *see also* Ex. 1 at 50. Arthralgia of multiple joints was still listed as part of Petitioner's active problems as of September 28, 2015, with Petitioner's complaint of bilateral wrist pain documented in the HPI. Tr. at 154; *see also* Ex. 1 at 83. Dr. Wilson agreed this was the result of vaccination. On December 9, 2015, arthralgias is under Petitioner's active problems list but there was no specific mention of arthralgias in his HPI, assessment, discussion, or summary. Tr. at 154; *see also* Ex. 1 at 89. Dr. Wilson stated he did not credit the various lists generated in electronic medical records if they do not correlate with a current complaint in the HPI. Tr. at 155.

V. Applicable Law

A. Petitioner's Burden in Vaccine Program Cases

Under the Vaccine Act, a petitioner may prevail in one of two ways. First, a petitioner may demonstrate that she suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the time period provided in the Table. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed in the Vaccine Injury Table, a petitioner may demonstrate that she suffered an "off-Table" injury. § 11(c)(1)(C)(ii).

For both Table and non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010); *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records of by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Secretary of Health and Human Services*. 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioner establish by preponderant evidence that the vaccinations he received caused her injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for

the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioner must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Hum. Servs*., 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility … in many cases may be enough to satisfy *Althen* prong one" (emphasis in original)), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017). But this does not negate or reduce a petitioner's ultimate burden to establish her overall entitlement to damages by preponderant evIdence. *W.C. v. Sec'y of Health & Hum. Servs*., 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, because they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing … that mandates that the testimony of a treating physician is sacrosanct–- that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record -- including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs*., 100 Fed. Cl. 742,

749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Hum. Servs*., No. 06-522V 2011 WL 1935813 at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs*., 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff'd without op.,* 503 F. App'x 952 (Fed. Cir. 2013). *Koehn v. Sec'y of Health & Hum. Servs*., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Analysis of Fact Evidence

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 413, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records created contemporaneously with the events they describe are generally trustworthy because they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions," where "accuracy has an extra premium." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378 (Fed. Cir. 2021) citing *Cucuras*, 993 F.2d at 1528. This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825 at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) *mot. for rev. denied*, 142 Fed. Cl. 247, 251-52 (2019), *vacated on other grounds and remanded*, 809 Fed. Appx. 843 (Fed. Cir. Apr. 7, 2020).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475 at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony–- especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; see also *Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475 at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez*, 2013 WL 1880825 at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611 at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *LaLonde v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of his or her claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (*citing Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). "The *Daubert* factors for analyzing the reliability of testimony

are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora. *Daubert* factors are employed by judges to exclude evidence that is unreliable and potentially confusing to a jury. In Vaccine Program cases, these factors are used in the weighing of the reliability of scientific evidence. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate persuasiveness and reliability of expert testimony has routinely been upheld. *See*, e.g., *Snyder*, 88 Fed. Cl. at 743. In this matter, (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). A "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Id.* at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. Consideration of Medical Literature

Finally, although this decision discusses some but not all of the medical literature in detail, I have reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Hum. Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

VI. Analysis

Because Petitioner does not allege an injury listed on the Vaccine Injury Table, his claim is classified as "off-Table." As noted above, to prevail on an "off-Table" claim, Petitioner must prove by preponderant evidence that he suffered an injury and that this injury was caused by the vaccination at issue. *See Capizzano*, 440 F.3d at 1320.

A. Diagnosis

As a threshold matter, a petitioner must establish he suffers from the condition for which he seeks compensation. *Broekelschen*, 618 F.3d at 1346. "The function of a special master is not to 'diagnose' vaccine-related injuries, but instead to determine 'based on the record as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner]'s injury.'" *Andreu v. Sec'y of Health & Hum. Servs*., 569 F.3d 1367, 1382 (Fed. Cir. 2009) (quoting *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994)). "Although the Vaccine Act does not require absolute precision, it does require the petitioner to establish an injury – the Act specifically creates a claim for compensation for 'vaccine-related injury or death.'" *Stillwell v. Sec'y of Health & Hum. Servs*., 118 Fed. Cl. 47, 56 (2014) (quoting 42.U.S.C. § 300aa-11(c)). Accordingly, the Federal Circuit has concluded that it is "appropriate for the special master to first determine what injury, if any, [is] supported by the evidence presented in the record" before applying a causation analysis pursuant to *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274 (Fed. Cir. 2005). *Lombardi v. Sec'y of Health & Hum. Servs*., 656 F.3d 1343, 1351-53 (Fed. Cir. 2011).

Petitioner's alleged vaccine injury has shifted throughout the course of this litigation. The experts have discussed different potential diagnoses, including TM, brachial neuritis, CFS, SIRS, reactive arthritis, arthralgia, and peripheral polyneuropathy. However, Petitioner's post-hearing brief and post-hearing reply brief eliminated many of these conditions from consideration. Petitioner now contends that he suffers from arthralgias that resulted from a severe inflammatory reaction caused by the Tdap vaccine. Pet'r's Post-Hearing Brief at 1; Pet'r's Reply Brief at 3.

Respondent asserts that Petitioner's "non-specific inflammatory response is not a cognizable injury." Respt's Brief at 29. Although Respondent does not specifically state that arthralgia is not a cognizable injury, I will briefly analyze this issue.

In *Lombardi v. Secretary of Health and Human Services*, the petitioner contended that she suffered from three different and distinct medical conditions: transverse myelitis, chronic fatigue syndrome, and systemic lupus erythematosus. *Lombardi v. Sec'y Health & Hum. Servs.*, 656 F.3d 1343, 1352 (Fed. Cir. 2011). Her treating physicians did not agree on a diagnosis, and even her experts differed with one another. *Id.* Ultimately, the court agreed with the special master that petitioner had not established she suffered from any of these conditions by preponderant evidence. The Federal Circuit held that the Vaccine Act "places the burden on the petitioner to make a showing of at least one defined and recognized injury … not merely a symptom or manifestation of an unknown injury." *Id.* at 1353.

In *Lasnetski v. Secretary of Health and Human Services*, the Court of Federal Claims

determined the special master was not arbitrary and capricious in concluding that sensory dysesthesia[8] and an "idiosyncratic severe reaction to vaccination" were not defined and recognized injuries, but instead were descriptions of symptoms. *Lasnetski v. Sec'y of Health & Hum. Servs.*, 128 Fed. Cl. 242, 263-64 (2016); *aff'd in non-precedential op.*, 696 Fed. App'x 497 (Fed. Cir. 2017). In that case, the Respondent's expert specifically testified that sensory dysesthesia and an idiosyncratic severe reaction to vaccination were descriptions of symptoms and not recognized injuries. *Id.* at 262. No such evidence was presented in the case at bar. The Court, in addressing *Lombardi*, noted that a vaccine injury cannot merely be a symptom of an unknown injury because "a symptom or manifestation could indicate any number of different underlying injuries, each with its own pathology, making it impossible for the court to accurately determine causation." *Id.*

The case at bar is similar to *Lombardi* in that Petitioner's treating physicians and her expert discuss several different diagnoses. The different diagnoses proposed by both the treating doctors and Dr. Shafrir reinforce the point that Petitioner's clinical picture was less than clear. However, in this case, unlike in *Lombardi*, the evidence supports a finding that Petitioner actually suffered from several distinct conditions. For example, Dr. Wilson testified that Petitioner's GI issues, to include loose stool, abdominal bloating, and liver failure were likely caused by his unnecessary prescription for antibiotics. Tr. at 145. Petitioner also suffered from fatigue after developing mononucleosis as a teenager. Wilson Rep. at 5. Importantly, however, there is no dispute that Petitioner suffered from arthralgia. The fact that Petitioner experienced other medical problems in addition to arthralgia does not mean that a diagnosis of arthralgia must explain his entire clinical picture. Further, a diagnosis of arthralgia does not frustrate the court's ability to determine causation. *Lasnetski*, 128 Fed. Cl. at 262.

Petitioner's treating physicians repeatedly diagnosed him with arthralgia. *See* Ex. 1 at 33 (May 23, 2015 medical record where Petitioner is assessed with "polyarthralgia"); Ex. 1 at 40 (medical record from May 26, 2015 where Dr. Wilcox assessed Petitioner with "arthralgia of multiple sites"); Ex. 1 at 43 (June 5, 2015 medical record where Dr. Wilcox diagnosed Petitioner with "arthralgia of multiple sites"); Ex. 1 at 48 (July 9, 2015 medical record where Dr. Wilcox assessed Petitioner with "arthralgia of multiple sites"); Ex. 1 at 51 (July 29, 2015 medical record where Dr. Wilcox assessed Petitioner with "arthralgia of multiple sites"). The fact that Petitioner's treating physicians diagnosed arthralgia suggests that it is a medically recognized injury.

Additionally, on several occasions, these diagnoses of arthralgia were accompanied by diagnostic code 719.49. *See e.g.*, Ex. 1 at 40, 43, 48, 51. This code is from the ICD-9 and is for "pain in joint, multiple sites."[9] The ICD-9, or the International Classification of Diseases is "a complex and evolving international coding system utilized by patient care providers to identify the condition or conditions suffered by their patients." *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877, at *5 (Fed. Cl. Spec. Mstr. May 30, 2013); *mot. for rev. denied*, Dec. 3, 2013, *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014). The fact that there is a specific ICD code for

[8] The "distortion of any sense, especially of that of touch." DORLAND'S, www.dorlandsonline.com/dorland/definition?id=15186 (last visited April 22, 2024).

[9] ICD-9-CM Diagnosis Code 719.49: Pain in joints, multiple sites. ICD9DATA, http://www.icd9data.com/2015/Volume1/710-739/710-719/719/719.49.htm (last visited April 23, 2024).

arthralgia further suggests that it is a cognizable injury and not merely a symptom of an unknown condition.

Based on the above, I conclude that Petitioner's diagnosis of arthralgia is supported by the record, and further, that it is a medically recognized injury.

B. Severity Requirement

The Vaccine Act includes a "severity requirement," which requires a petitioner to demonstrate that they:

> (i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention.

§11(c)(1)(D). "'Residual' suggests something remaining or left behind from a vaccine injury." *Wright v. Sec'y of Health & Hum. Servs.*, 22 F.4th 999, 1005 (Fed. Cir. 2022).

Respondent contends that Petitioner has not suffered from a vaccine related injury for more than six months. Resp't's Brief at 37-42. Six months after vaccination is November 20, 2015. I find the evidence supports that Petitioner continued to experience the residual effects of his arthralgias more than six months post vaccination.

Petitioner testified that as of the date of the entitlement hearing, he still experienced joint pain in his wrists and hands. Tr. at 29. This testimony of continuing joint pain is consistent with the medical records detailed below.

Petitioner's symptoms began on May 22, 2015, when he experienced neck pain and stiffness as well as difficulty moving his right hand. Ex. 1 at 22. His symptoms continued the next day and included neck stiffness and bilateral hand and arm weakness and pain. Ex. 1 at 31-33. Petitioner's CRP was elevated at 90.70 as was his white blood count. *Id.* at 34, 36. The doctor noted "most likely this is an inflammatory reaction to the tetanus shot he received." The doctor's final impression was "polyarthralgia" and bilateral arm weakness." *Id.* at 33.

Petitioner returned to his PCP, Dr. Wilcox, on May 26, 2015. Petitioner described that he was stiff and sore and that he was experiencing migratory swelling and arthralgias. Ex. 1 at 39. On physical examination, Petitioner had erythema and swelling of his left forefinger. *Id.* at 40. Dr. Wilcox prescribed a prednisone taper. *Id.*

Petitioner returned to Dr. Wilcox on June 5, 2015. Ex. 1 at 42-44. Dr. Wilcox assessed Petitioner as having "arthralgia of multiple sites" and noted that he was experiencing "[c]ontinued generalized and migratory arthralgias following a tetanus vaccination." *Id.* at 43. Dr Wilcox observed that Petitioner's "clinical course continues to be most suggestive of a reaction to his vaccination." *Id.*

On June 30, 2015, Dr. Moore. observed that Petitioner was feeling better, but that as he tapered from prednisone, some of his symptoms had again worsened. Ex. 1 at 45. She documented mild synovitis in his hands. *Id.*

On July 29, 2015, Petitioner returned to Dr. Wilcox one week after completing his prednisone taper. The medical record notes that Petitioner's arthralgias were improving but that there was some residual wrist discomfort. Ex. 1 at 50. Dr. Wilcox documented "mild redness in the outer aspect of both wrists" on physical exam. *Id.* at 51.

Petitioner visited Dr. Sislow on September 28, 2015. Ex. 1 at 83. During this visit, Petitioner complained of mild bilateral wrist pain. *Id.*

The medical records listed below reflect treatment conducted after November 20, 2015, and thus are relevant to the six-month severity issue.

On December 30, 2015, Petitioner returned to Dr. Wilcox. Ex. 1 at 127. Dr. Wilcox noted that Petitioner continued "to feel poorly." The Review of Systems listed joint pain, swelling or redness of joints, and muscle pain. *Id.* at 128.

On February 29, 2016, Petitioner visited Dr. Krajcer, a rheumatologist at the Polyclinic. Ex. 5 at 2. On physical exam, Petitioner was noted to have localized tenderness to palpation in his peripheral joints, shoulders, and knees. *Id.* at 5. Dr. Krajcer's impression was systemic inflammatory response syndrome ("SIRS") subsequent to a vaccination with reported migratory arthritis and spondylitis symptoms in the neck. *Id.* at 11. Dr. Krajcer subsequently emailed Petitioner a message on March 11, 2016 suggesting that his SIRS "may gradually burn out." *Id.* at 20. The statement that his inflammatory condition "may" burn out suggests that it had not yet subsided.

On March 18, 2016, Petitioner visited Dr. Yang, a neurologist at the Polyclinic. Ex. 5 at 34-37. Dr. Yang noted that Petitioner continued to have "remarkable weakness of the arms and legs." *Id.* at 35.

Several of the medical records after November 20, 2015 demonstrate that Petitioner continued to suffer from arthralgias or residual symptoms associated with arthralgias. These records are consistent with his testimony at the entitlement hearing and preponderantly establish that Petitioner suffered from the residual effects of his condition for more than six months.

C. *Althen* Prong One

In the context of the Program, "to establish causation, the standard of proof is preponderance of evidence, not scientific certainty." *Langland v. Sec'y of Health & Hum. Serv.*, 109 Fed. Cl. 421, 441 (2013). Petitioner's burden under *Althen*'s first prong is to provide a medical theory causally connecting the vaccination and the injury. *Id.* This theory must be sound and reliable. *Boatmon*, 941 F.3d at 1359.

In his expert report, Dr. Wilson opined that "[s]ystemic inflammation with arthralgias and myalgias are common phenomena that are associated with a wide variety of infectious triggers. They can also occur after many vaccinations, including Tdap, but they are short-lived (days)." Wilson Rep. at 6. Dr. Wilson cited to the Hervé article in support of this point, which described that "[t]he mediators and products of inflammation at a localised site in the body may spill into the circulation and can affect other body systems causing systemic side-effects." Hervé et al., *The how's and what's of vaccine reactogenicity*, 4 NPJ VACCINES 39, 1-11 (2019) (filed as Ex. E) (hereinafter "Hervé"). Dr. Wilson conceded that Tdap vaccine "can cause" arthralgias, and the Hervé article supports this opinion.[10]

During the entitlement hearing, Dr. Wilson testified that the Tdap vaccination caused Petitioner's arthralgia in July and September of 2015. *See* Tr. at 152-54 (In discussing the September 28, 2015 medical record, the following exchange occurred; Q: "the arthralgia listed under active problems, do you attribute that to the same vaccine reaction that you attributed the July 29 note to?" A: "Yes").

Dr. Wilson's concession that Petitioner's Tdap vaccine "did cause" his initial arthralgias inherently means that he agrees the Tdap vaccine "can cause" arthralgias. *Caves v. Sec'y of Dept. of Health & Hum. Servs.*, 100 Fed. Cl. 119, 145 (2011) ("[A] statement that a vaccine did in fact cause an injury presupposes that the vaccine is capable of causing that injury."); *aff'd*, 463 Fed. App'x. 932 (Fed. Cir. 2012); s*ee also Capizzano*, 440 F.3d at 1326 (stating that evidence relevant to one *Althen* prong may be relevant to another *Althen* prong); *Pankiw v. Sec'y of Health & Hum. Servs.*, No. 15-1082V, 2021 WL 5578387, at *8 (Fed. Cl. Spec. Mstr. Nov. 2, 2021) (noting that a doctor's statement that a vaccine did cause the petitioner an injury implies that that vaccine can cause that injury).

Accordingly, causation is conceded; Petitioner has presented preponderant evidence in support of the first *Althen* prong.

D. *Althen* Prong Two

Under *Althen's* second prong, a petitioner must "prove a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. The sequence of cause and effect must be "'logical' and legally probable, not medically or scientifically certain." *Id.* A petitioner is not required to show "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." *Id.* (omitting internal citations). *Capizzano v. Sec'y of Health & Hum. Servs*., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, circumstantial evidence and reliable medical opinions may be sufficient to satisfy the second *Althen* prong. *Isaac v. Sec'y of Health & Hum. Servs.*, No. 08-601V, 2012 U.S. Claims LEXIS 1023 at *75 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for rev. denied*, 108 Fed. Cl. 743 (Fed. Cl. 2013); *aff'd* 540 Fed. App'x 999 (Fed. Cir. 2013).

[10] I additionally note the Adacel package insert documents that 9.1% of adults aged 18-64 experienced sore and swollen joints in days 0-14 after Adacel vaccination. Ex. 50 at 9. Of that number, .5% reported "severe" symptoms. *Id.*

I first note that Petitioner's presentation is consistent with a vaccine reaction. He experienced weakness, joint pain, stiffness, and swelling that began two days after his Tdap vaccination. On May 23, 2015, Petitioner's CRP level was markedly elevated at 90.70 (reference range ≤ 3.0 mg/L). Ex. 1 at 36. His white blood count was also high at 13.8 (reference range 4.0-11.0 kK/uL). *Id.* at 34. Elevated CRP and white blood count support the existence of active inflammation. Tr. at 38, 138.

In addition, Petitioner's treating physicians consistently attributed his arthralgias to the Tdap vaccination. On May 26, 2016, Dr. Wilcox diagnosed Petitioner with "arthralgia of multiple sites" and noted "[i]t appears that he is suffering from a reaction to his Adacel vaccination. His current symptoms are reported side effects and he has had extensive evaluation otherwise." Ex. 1 at 40. On June 5, 2015, Dr. Wilcox again opined that "[h]is clinical course continues to be most suggestive of a reaction to his vaccination." *Id.* at 43. On June 30, 2015, Petitioner visited Dr. Moore, who assessed him with drug toxicity and noted a "[p]robable reaction to the Tdap [vaccine]." *Id.* at 45. On September 28, 2015, Dr. John Sislow noted in the medical record "[t]his 40 year old physical therapist received a tdap (Adacel) injection this past spring and had a profound adverse reaction including diffuse joint stiffness." *Id.* at 83. On February 29, 2016, Dr. Krajcer (a rheumatologist) found that Petitioner suffered from a "[s]ystemic inflammatory response syndrome last [M]ay subsequent to a vaccination with reported migratory arthritis, spondylitis symptoms (neck)." Ex. 5 at 11. Dr. Krajcer messaged Petitioner on March 11, 2016 and stated, "I suspect that this systemic inflammatory response syndrome of sorts that started after your vaccination to Tda[p] may gradually burn out. … The Tdap [v]accination is on your allergy list here and should be in any other healthcare setting." *Id.* at 20. On February 15, 2022, Dr. Wilcox noted that Petitioner had a "[p]revious reaction to tetanus vaccination" and noted that he should "avoid vaccinations for now." Ex. 54 at 11.

In weighing evidence, special masters are expected to consider the views of treating doctors. *Capizzano*, 440 F.3d at 1326. The views of treating doctors are often persuasive because the doctors have direct experience with the patient whom they are treating. *See McCulloch v. Sec'y of Health & Hum. Servs.*, No. 09-293V, 2015 WL 3640610, at *20 (Fed. Cl. Spec. Mstr. May 22, 2015). I find the views of Petitioner's treating physicians to be persuasive, and help Petitioner to establish that the vaccine "did cause" his condition.

Consistent with the opinions of Petitioner's treating doctors, both Dr. Shafrir and Dr. Wilson testified that Petitioner's arthralgias were caused by his Tdap vaccination. Tr. at 68-69 (Dr. Shafrir opining that Petitioner's initial symptoms to include pain and inflammation was a direct result of vaccination), Tr. at 152-54 (Dr. Wilson conceding that Petitioner's arthralgias that he experienced in July and September were caused by vaccination).

For the reasons articulated above, I find that Petitioner has preponderantly demonstrated that his vaccination caused his arthralgias, and has thus established the second prong of *Althen*.

E. *Althen* Prong Three

The timing prong contains two parts. First, a petitioner must establish the "timeframe for

which it is medically acceptable to infer causation" and second, he must demonstrate that the onset of the disease occurred in this period. *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542-43 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff'd without op.*, 503 F. App'x 952 (Fed. Cir. 2013).

Petitioner received his Tdap vaccine on May 20, 2015. There is no dispute that he began to experience pain and stiffness two days later. Dr. Shafrir testified that this onset interval is medically appropriate and implicates the vaccine as causal. Tr. at 77. Dr. Wilson agreed. He opined as follows: "I agree with the petitioner's expert that Mr. Schwarz had an acute inflammatory reaction in the immediate aftermath of his vaccination associated with elevated inflammatory markers in the blood that caused pain and discomfort in various joints, **but even though there was a temporal association between these symptoms and the vaccination**, this does not prove causation." Wilson Rep. at 7 (emphasis added). Dr. Wilson conceded the temporal association between vaccination and onset of arthralgias.[11] Further, the Hervé article supports an onset of symptoms consistent with an innate immune response. Two days is within this window. *See generally*, Hervé; *see also* Tr. at 150 (Dr. Wilson testifying that the innate immune response occurs within the first three days after vaccination). Thus, Petitioner has presented preponderant evidence in support of the third *Althen* prong.

VII. Conclusion

Upon careful evaluation of all the evidence submitted in this matter, including the medical records, the affidavits and testimony, as well as the experts' opinions and medical literature, I conclude that Petitioner has established entitlement to compensation. An order regarding damages will issue shortly.

IT IS SO ORDERED.

s/ Katherine E. Oler
Katherine E. Oler
Special Master

[11] Even though Dr. Wilson did not state that the temporal interval was "medically appropriate", that is the clear implication of his statement. Indeed if he thought the timing was not appropriate to implicate the vaccine, he would have said so.